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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,249	12/05/2001	Michael John Stephen Austin	S63.2-10014	8321

490 7590 02/26/2003

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/683,249	AUSTIN, MICHAEL JOHN STEPHEN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sarah K Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 4,10-19,22-28,30 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,20,21,29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2-4</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 4,10-19,22-28,30, and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6, and the examiner has responded by including claims 1-3 as generic.

### ***Specification***

2. The disclosure is objected to because of the following informalities: the detailed description makes reference to the claims on pages 18 and 19. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3,5-9,20,21 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,264,687 to Tomonto.

Regarding claims 1-3 and 20, Tomonto discloses a stent that has three balloon expandable, but not self-expanding segments (20,30,40), as shown in Figure 2. Two self-expanding segments (80,90) are located between the balloon expandable segments. Tomonto describes the balloon expandable sections (20,30,40) as rigid and plastically deformable (column

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4, line 43). The segments (80,90) are formed only of a superelastic material, such as Nitinol, so they are inherently self-expanding (column 5, line 20).

Regarding claim 5: The language of claim 5 is very broad, so the best reasonable interpretation was given the claim. Applicant only explains that an *island* may be only one self-expanding cell (page 8, line 8), or simply a plurality of connected self-expanding cells. Applicant further explains that the *islands* can have any shape (page 9, line 5). Given this, the stent of Tomonto meets the limitations of claim 5. The balloon expandable segments (20,30,40) clearly have *cells*, as outlined on the attachment. The self-expanding segments (80,90) have *cells*, which are outlined more clearly in the attachment. These *cells* are formed by the self-expanding material that lies partly underneath the balloon expandable material. Since the main portion of the self-expanding cells is made solely of the self-expanding material, the self-expanding cells are considered to be in between the balloon expandable cells. The self-expanding cells are connected to make up intermediate "islands" (80,90), which are surrounded by the balloon expandable segments (20,30,40).

Regarding claims 6-9 and 21: Since there are two "islands" of self-expanding cells, the stent has a *plurality* of islands. The stent has three, or a plurality, of balloon expandable sections. The islands are regularly distributed over the stent, and there are more balloon expandable cells than self-expanding cells.

4. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,409,750 to Hyodoh et al.

Hyodoh discloses a stent (10) that can be made of a shape memory material, such as FeMnSiCrNi (column 2, line 12; column 7, lines 31-35).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto in view of Hyodoh.

Tomonto includes all the limitations of claim 32, except for the shape memory metal being FeMnSiCrNi stainless steel. Hyodoh teaches that FeMnSiCrNi is a shape memory metal used for self-expanding stents, and is an equivalent substitute for nitinol (column 2, lines 8-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the self-expanding portion of Tomonto from FeMnSiCrNi, as taught by Hyodoh, as this just an alternate shape memory metal to nitinol.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto in view of US Patent No. 6,096,070 to Ragheb et al.

Tomonto includes all the limitations of claim 29, except for a biological coating on the stent. Ragheb teaches that is desirable to apply biological coating to stents in order to treat conditions and diseases, such as thrombosis (column 2, lines 41-67). Ragheb lists many biological materials that are currently incorporated in stent coatings in column 3. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a biological coating on the stent of Tomonto, as taught by Ragheb, in order to prevent and treat conditions and diseases of blood vessels.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6, 488, 702 to Besselink and US 5,601,593 to Freitag disclose stents that have cellular structure and both balloon expandable and self-expanding members.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

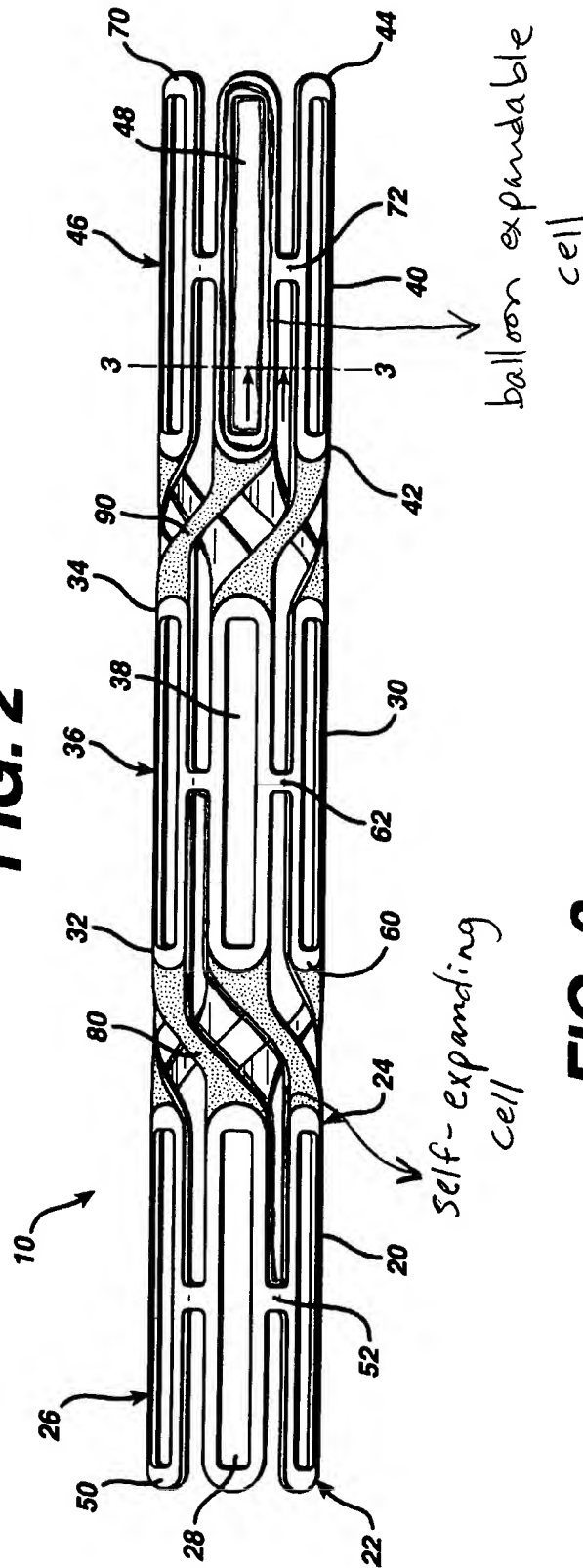
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb  
Examiner  
Art Unit 3731

SW  
February 21, 2003

  
Michael Milano  
Supervisory Patent Examiner  
Art Unit 3700

**FIG. 2**



**FIG. 3**

